HFI-35 M636N

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1123565

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 21, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. David Wine, President
Advanced Health Care Services, Inc.
58 N. Washington Avenue
Pulaski, Virginia 24301

Dear Mr. Wine:

The Food and Drug Administration (FDA) conducted an inspection of your Martinsville, Virginia facility on May 5-7, 1998. During the inspection, the following deviations from Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to have the appropriate documentation to demonstrate that each batch of Oxygen USP is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess prior to release.

2. Failure to adequately calibrate or to document the routine maintenance and calibration of the equipment used to test Oxygen USP, including the oxygen analyzer, pressure and vacuum gauges, and thermometers.

3. Your employees failed to document pre-fill, fill, and post-fill operations on each cylinder filled.

4. Failure to establish batch production records for each batch of Oxygen USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance and was verified for accuracy and completeness by a second individual.

At the conclusion of the inspection, Ms. Dana L. Turner, Supervisor, was given a written list of inspectional observations (FDA-483, enclosed) which was discussed with her.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a document provided by FDA National Expert, Mr. Duane Sylvia, titled "FRESH AIR '98" which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Carl E. Draper
Acting Director, Baltimore District

Enclosures

cc: Virginia Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717